REMARKS

Status of the claims

Claims 1-35 are pending in the application. Claims 32-35 are withdrawn from consideration and herein canceled. Claims 1-35 are rejected. Claim 1 is currently amended. No new matter is added.

Claim amendments

Claim 1 is currently amended to overcome rejections under 35 USC §102. Claim 1 is amended to specify that each electrode pair on the device is in proximate relationship to a force transducer and that the force transducers and electrode pairs are disposed annularly around the insertable section of the probe. The basis for this amendment is on page 12, lines 9-16 of the specification. No new matter is added.

Objection to the drawings

The Examiner states that Figure 4 is intended to be in color and that color drawings are not accepted unless a petition filed under 37 CFR 1.84(a) is granted.

A color version of figure 4 along with a petition under 37 CFR 1.84(a) and fee set forth in 37 CFR 1.17(h) will be submitted by the Applicants on the allowance of this application.

Claim rejection under 35 USC §102

Claims 1, 3, 21-24, 27 and 30 are rejected under 35 USC §102(b) as being anticipated by **Johnson** et al. (US 4881526). Applicants respectfully traverse this rejection.

The Examiner states that with respect to claims 1, 3, 27 and 30, **Johnson** et al. discloses an intravaginal muscle diagnosis/treatment device comprising a rigid disposable or non-disposable insertable cylindrical probe with a rounded tip, a plurality of force transducers, a plurality of stimulation electrode pairs, a plurality of amplifiers and a probe position holding means securing said probe within a body lumen. The Examiner further states that with respect to claims 21-24, **Johnson** et al. discloses disposing single and multiple rows of piezoelectric transducers (column 6 lines 37-40) and electrical stimulation electrodes in a permanently fixed annularly disposed relationship (column 3 lines 5-8). Applicants respectfully disagree.

Johnson et al. discloses an intravaginal electrode assembly, which includes an elongated and generally cylindrical carrier having a tip at a distal end and an extended lip at a proximal end. A pair of motor electrodes are positioned adjacent one another on an exterior surface of the elongated carrier and sensory stimulation means are mounted on the carrier adjacent to the lip portion of the carrier. Motor electrode terminal means are coupled to the pair of motor electrodes and receive motor receptor electrical stimulation signals. Sensory receptor stimulation signals are coupled to the sensory stimulation means through the sensory stimulation terminal means. The sensory stimulation means includes a pair of electrodes coupled to the sensory stimulation terminal and/or an oscillatory transducer such that it receives oscillatory drive signals from the sensory stimulation terminal (col. 2, line 57- col. 3, line 22).

Applicants' invention is a luminal directional force measurement and electrical stimulation device. To enable these functions the device is equipped with a plurality of force transducers, a plurality of electrodes, a plurality of instrumentation for amplifying signals and a means to hold the probe position within the body lumen. Thus the device is equipped not only for stimulation of luminal muscle but also to detect localized areas of muscle weakness within the lumen. Measuring localized areas of muscle weakness is important so that only an area that shows muscle weakness is targeted fro stimulation based exercise regime.

Each electrode pair in the instant probe is in proximate relation to a force transducer as recited in amended claim 1 (see claim amendments section). The advantage of this arrangement is that in addition to delivering regional electrical stimulus via different electrode pairs the regional pressure measurements during stimulation is also recorded via a regional force transducer. To detect the signals from the various transducers the device is equipped with a plurality of signal amplifiers. Thus the device enables assessment of the actual muscle response in the area subjected to the electrical stimulation.

The intravaginal electrode and stimulating system of **Johnston** et al. is not specifically designed to measure the force generated on electrical stimulation by the motor or sensory stimulation electrodes. So even thought this system has a plurality of electrode pairs, it does not have a plurality of force transducers such that each electrode pair is in proximate relationship to one force transducer. The system disclosed by Johnston et al., in one embodiment, has an oscillatory transducer (one transducer and not a plurality of transducers as stated by the Examiner on page 3 of the Office Action) for mechanical stimulation of the tactile receptors in the vagina. This transducer is connected to the sensory stimulation control circuitry that includes oscillatory transducer signal generator, oscillatory transducer parameter control circuitry and oscillatory transducer control switches (col. 6, lines 34-52). The oscillatory transducer and its control circuitry are thus not equipped to measure localized contractile force generated by the vaginal muscle on stimulation by the motor or sensory electrodes. This is taught only in the Applicants invention.

At minimum absent a teaching of the presence of a plurality of electrode pairs such that each electrode pair is in proximate relation to one force transducer, Johnston et al. cannot anticipate currently amended claim 1. Claims 3, 21-24, 27 and 30 depend either directly or indirectly from claim 1 and so are also not anticipated by Johnston et al. Accordingly Applicants respectfully request that the rejection of claims 3, 21-24, 27 and 30 under 35 USC §102(b) as being anticipated by **Johnson** et al. be withdrawn.

Claims 1-4, 20-24, 26-27 and 30 are rejected under 35 USC §102(b) as being anticipated by **Hamedi** et al. (5662699). Applicants respectfully traverse this rejection.

The Examiner states that with regards to claims 1, 3, 26-27 and 30, **Hamedi** et al. discloses an intravaginal muscle diagnosis/treatment device comprising a rigid disposable or non-disposable insertable cylindrical probe with a rounded tip, a plurality of force transducers, a plurality of stimulation electrodes, a plurality of amplifiers disposed within the non disposable section and a probe position holding means securing said probe within a body lumen. The Examiner states that with respect to claims 2 and 4, **Hamedi** et al. discloses a disposable ribbed sheath inherently capable of measuring insertion depth and an electrical interface unit comprising amplifiers generators, parameter control and a computer connection means. The Examiner further states that with respect to claims 20-24, **Hamedi** et al. discloses disposing on a sheath single and multiple rows of force measuring transducers and electrical electrodes in a permanently fixed annularly disposed relationship. Applicants respectfully disagree.

Hamedi et al. discloses a device for stimulating and monitoring the exercise of muscles near a body cavity by transmitting electrical energy between an electrical source or processor and the wall of the body cavity. A flexible airtight sheath with a resilient skeleton and outer conductive bands is collapsed by vacuum and inserted into the body cavity. Air is allowed to enter so that the skeleton expands against the body cavity wall (Abstract). An air pump is required to enable proper function of the device.

The Examiner states that 32 and 36 in the probe disclosed by **Hamedi** et al. are force transducers. However Applicants would like to respectfully point out that 32 and 36 along with 34 and 38 are electrode bands and not force transducers (col. 5, lines 1-3). Figure 17 in **Hamedi** et al. illustrates the electrical circuits formed with electrodes 32, 34, 36, 38 when the device is used in electrotherapy. In electrotherapy, the electrical device 78 is typically a pulse generator capable of forming a train of electrical pulses, which are beneficial in the treatment of female urinary incontinence. In electromyography feedback usages, the electrical device 78 typically amplifies the electrical signals received from the body cavity wall and transforms them into auditory, tactile or visual display (col. 7 line 50-col. 8 line12). There are no force transducers in proximate relation with the electrodes 32, 34, 36 or 38 for a direct measurement of muscle force exerted by luminal wall muscle.

The airtight sheath disclosed by **Hamedi** et al. may comprise ribs to enhance the electrical and mechanical contact between the sheath and the luminal wall. **Hamedi** et al. also state that the ribs need not be continuous and breaks or cross section changes in the ribs may be employed to control the force with which the ribs attempt to expand and the collapsed shape of the ribs (col. 5, lines 22-29). This clearly indicates that the ribs are not designed to measure insertion depth of the sheath in the body cavity. To measure insertion depth the ribs would have to be placed at a calibrated distance and cannot be discontinuous as suggested above.

Applicants' device does not require an air pump for proper functioning of the device nor does the disposable sheath of the instant device require a port for pumping in air. Furthermore Applicants' device comprises a plurality of electrode pairs such that each electrode pair is in proximate relation to one force transducer for measuring muscle strength at different points within the lumen. In a preferred embodiment **Hamedi** et al. disclose that the electrodes may be arranged as a continuous conductive band around the sheath of the probe. This design in itself precludes the measurement of electrical activity at specific points along the lumen circumference as a continuous conductive band would measure the electrical activity along the entire zone that is in contact with this conductive band. Also, the device disclosed by **Hamedi** et al. does not have a single force transducer. Thus the instant device is substantially different from the device taught by **Hamedi** et al. At minimum absent a teaching of a plurality of electrode pairs such that each electrode pair is in proximate relation to one force transducer, **Hamedi** et al. cannot anticipate amended claim 1. Claims 1-4, 20-24, 26-27 and 30 depend either directly or indirectly from claim 1 and are thereby not anticipated by **Hamedi** et al. Accordingly Applicants respectfully request that the rejection of claims 1-4, 20-24, 26-27 and 30 under 35 USC §102(b) be withdrawn.

Claim rejections under 35 USC §103

Claims 5-6, 15-19, 25, and 32 are rejected under 35 USC §103(a) as being unpatentable over **Hamedi** et al. in view of **Sarvazyan** (US 5836894) Applicants respectfully traverse this rejection.

The Examiner states that with respect to claims and 6, **Hamedi** et al. discloses the claimed *supra* measurement probe except for providing battery power to the electrical components and a battery powered portable computer for signal processing. Sarvazgyan remedies this deficiency by teaching an *invivo* measurement probe comprising an array of strain gauge pressure sensors having controlling battery powered portable electronics including a six channel amplifier, an A/D converter, a computer and computer connection as shown in Figure 18. The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invivo measurement probe as taught by **Hamedi** et al., with Sarvazgyan for the purpose of testing/measuring parameters of a patient via a measurement device and portable electronics in a remote and/or comfortable environment.

The Examiner further states that for claims 15-16, **Hamedi** et al. discloses the claimed invivo measurement/stimulation probe except for the means of holding the probe comprising a base connection housing having a probe connector connecting the non-disposable section of the probe within said housing and axial displacement sensors. **Sarvazyan** teaches an *supra* force measurement/stimulation probe comprising a probe holding means having a connector connecting the non-disposable section of the probe with the housing and further comprising axial displacement sensors. The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the *invivo* measurement probe as taught by **Hamedi** et al. with **Sarvazyan** for the purpose of housing a testing/measuring device that determines the parameters of a patient via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

The Examiner further states that for claim 17, **Hamedi** et al. discloses the claimed invivo measurement/stimulation probe except for the means of holding the probe comprising a probe base connection housing having a calibrated spring system resisting probe axial displacement. **Sarvazyan** teaches an invivo force measurement/stimulation probe comprising a probe holding means having a calibrated spring system resisting probe axial displacement. The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the probe as taught by **Hamedi** et al. with **Sarvazyan** for the purpose of housing and calibrating a device that determines the parameters of a patient via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

The Examiner states that with respect to claims 25, **Hamedi** et al. discloses the measurement/stimulation probe except for measuring radial force components. **Sarvazyan** teaches an invivo force measurement probe comprising an array of strain gauge pressure sensors for measuring the radial position and orientation of forces. The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the probe as taught by **Hamedi** et al. with **Sarvazyan** for the purpose of testing parameters via a measurement device configured to evaluate tissue motion when subjected to external stimuli.

With respect to claim 32, **Hamedi** et al. discloses the claimed invivo measurement probe except for simultaneously measuring pressure. **Sarvazyan** teaches an invivo force measurement probe comprising an array of strain gauge pressure sensors for measuring the radial position and orientation of forces. The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the probe as taught by **Hamedi** et al. with **Sarvazyan** for the purpose of testing parameters via a measurement device configured to evaluate tissue motion when subjected to external stimuli. Applicants respectfully disagree.

Sarvazyan discloses a pressure force sensing array to measure the surface stress pattern on soft tissues. The device disclosed by Sarvagyan comprises a probe, which includes a probe shaft, a position sensor for determining the position of the tip and an array of force sensors for determining the pattern of pressure from tissue deformed by the tip (Abstract). The tip of the probe is movable above and below the axis of the probe shaft. In its axial position, the tip can measure pressure from rising surfaces of the prostate parallel to the axis. When tilted above the axis, the tip can measure pressure from rising surfaces of the prostate, and when tilted below the axis, it can measure pressure from the falling surfaces of the gland (column 4, lines 56-62).

The probe disclosed by **Hamedi** et al. is substantially different from the instant probe as described *supra*. **Sarvazyan**'s teaching of a battery powered electronics and a computer does not make the probe design taught by **Hamedi** et al similar to that disclosed in the instant application. Furthermore the tensioning springs in **Sarvazyan**'s device functions to exert pressure on the tissue surface via the probe tip. The tensioning springs are further connected to a calibrated safety spring to ensure that the force experienced by a patient never exceeds certain safety limits (column 12, lines 59-65). The spring system in the Applicants' device is mainly to stabilize the probe position within the lumen. **Hamedi** et al. does not disclose or suggest the application of pressure either to stabilize the probe position or to stimulate tissue. So one skilled in the art would not be motivated to include a probe handle with the spring system as taught by **Sarvazyan** in the device taught by **Hamedi** et al. Even if this combination were devised it would still be different from the instant device as the probe taught by **Hamedi** et al. is substantially different from the instant probe.

Sarvazyan teaches the use of an array of pressure sensors to detect the force exerted by tissue. The pressure profile is minutely measured over an area to prepare a mechanical image of the tissue being probed. This necessitates the use of an array of pressure sensors rather than the use of individual pressure sensors/transducers. As an array is better equipped to simultaneously measure pressure at different points (separated by small distances) in a given area as opposed to individual force sensors/transducers that are arranged on a probe (as taught in the instant application). In

Sarvazyan's device, pressure exerted by different zones of the tissue is measured by displacing the probe tip along the axis of the probe shaft to change the position of the pressure sensor array. In the Applicants' device, pressure at various locations within the lumen is measured by a plurality of force transducers (individual force transducers and not an array) that are annularly disposed on the surface of the probe. As described *supra*, in a preferred embodiment, **Hamedi** et al. disclose the use of conductive bands on the probe sheath for either electrically stimulating or measuring electrical activity of luminal muscles. Thus **Hamedi** et al. does not specifically disclose stimulation of limited areas along the circumference of the lumen as a conductive band would stimulate the entire zone covered by the band. Thus even if one skilled in the art would be motivated to combine the electrodes of **Hamedi** et al. with a pressure sensor array as taught by **Sarvazyan** the probe thus formed would still be different from the instant probe.

In view of the arguments presented above it is clear that at minimum absent a teaching or suggestion of a plurality of force transducers and a plurality of electrode pairs wherein each electrode pair is in proximate relationship to a force transducer and wherein the force transducers and electrode pairs are annularly disposed on the insertable part of the probe, the combination of **Hamedi** et al. and **Sarvazyan** does not make claim 1 obvious. As claims 5-6, 15-19, 25 and 32 depend directly or indirectly from independent claim 1, the combination of **Hamedi** et al. and **Sarvazyan** cannot render claims 5-6, 15-19, 25 and 32 obvious. Accordingly, Applicants respectfully request that the rejection of claims 5-6, 15-19, 25 and 32 over 35 U.S.C. §103(a) be withdrawn.

Claims 7-14 and 18-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Hamedi** et al. in view of **Black** (US patent 6,926,006). Applicants respectfully traverse this rejection.

The Examiner states that for claims 7-8 and 14, **Hamedi** et al. disclose the claimed *supra* measurement probe except for the probe holding means comprising am examination platform with detachable probe holder that connects to the non-disposable section of the probe. The Examiner states that for claims 9-13, **Hamedi** et al. disclose the claimed *supra* measurement probe except for an examination platform placed on a bed, table or wall mounted comprising a first padded section, second padded section comprising detachable probe holder, handles disposed on first and second sections, and a hinge connecting said first and second sections whereby the platform folds into a parallel relation and is capable of being carried by handles. For claims 18 and 19, **Hamedi** et al. discloses the instant probe except for a connection housing attachable to a probe base connection housing attached to a spring attached to a cross-member and a support structure comprising a padded support for an individual's inner thigh.

The Examiner states that the invention by **Black** overcomes the deficiency in **Hamedi** et al.'s teaching. The Examiner states that **Black** teaches a probe holding means comprising a table and an adjustable probe holder in detachable engagement with the table. The Examiner further states that **Black** also teaches an examination platform capable of being placed on a bed or table comprising a first and second padded section with handles, detachable probe holder and a hinge connecting the first and second sections whereby the platform is inherently capable of folding into a parallel relation and carried by said handles. The Examiner states that **Black** further teaches an examination platform comprising a connection housing comprising a spring leaf attached to a cross-member attached to said connection housing and further comprising a support structure covered with pads inherently capable of supporting an individuals inner thigh. The Examiner concludes by stating that it would have been obvious to combine the teaching of **Hamedi** et al. with **Black** to provide a configurable probe holder and platform as taught by the instant application. Applicants respectfully disagree.

Black teaches a bench with a swinging seat comprising a pair of inverted U-shaped members forming front and rear legs and side rails above and between the front and rear legs. Front and rear cross members are fastened to extend between the front and rear legs. Front and rear seat mounting members are pivotally connected to the inverted U-shaped members. A seat attached to the front and rear seat mounting members is disposed between the first and second U-shaped members so that the seat is free to move forward and rearward. Pivoting is achieved by using a bracket interposed between each end of the seat mounting members and the adjacent inverted U-shaped member. An upper portion of each bracket is pivotally connected to the adjacent inverted U-shaped member while a lower portion of each bracket is pivotally connected to the seat mounting member (column 1, lines 44-61).

As detailed *supra*, **Hamedi** et al does not disclose the probe as described by the Applicants. The bench/platform as taught by **Black** comprises a seat that is free to move forward or rearward. Thus the platform as described by **Black** teaches away from the Applicants portable folding platform that is not designed to move in the forward or rearward direction. Furthermore the teaching in **Black** does not remedy the deficiency in the probe as taught by **Hamedi** et al. So even if one were motivated to combine the platform as taught by **Black** with the probe as taught by **Hamedi** et al. it would still not render the Applicants device obvious. At minimum absent a teaching or suggestion of a plurality of force transducers and a plurality of electrode pairs wherein each electrode pair is in proximate relationship to a force transducer and wherein the force transducers and electrode pairs are annularly disposed on the insertable part of the probe, the combination of **Hamedi** et al. and **Black** does not render claim 1 obvious. As claims 7-14 and 18-19 depend either directly or indirectly from claim 1, these claims are also not rendered obvious over the cited prior art. Accordingly, Applicants respectfully request that the rejection of claims 7-14 and 18-19 under 35 U.S.C. §103(a) be withdrawn.

Claims 28, 29 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Johnson** et al. Applicants respectfully traverse this rejection.

The Examiner states that **Johnson** et al. discloses the claimed invention including disposing the electrode in a proximal relation to the distal tip but does not expressly disclose the claimed probe diameter and length. The Examiner states that it would have been an obvious matter of design choice to modify **Johnson** et al. to obtain the invention as specified in the claims. Applicants respectfully disagree.

Johnson et al. is as described *supra*. The probe as taught by **Johnson** et al. does not anticipate or suggest the probe elements as taught by the Applicants. At minimum absent a teaching in **Johnson** et al. of a probe with a plurality of annularly disposed force transducers and electrode pairs such that each electrode pair is proximal to a force transducer, the instant probe is not obvious over **Johnson** et al. Even if the probe disclosed by **Johnson** et al. were tailored to the dimensions disclosed by the Applicants, it would still not render the Applicants invention obvious. Thus claim 1 is not obvious over **Johnson** et al. and claims 28, 29 and 31, which depend from claim 1 are also not rendered obvious over **Johnson** et al. Accordingly Applicants respectfully request that the rejection of claims 28, 29 and 31 under 35 U.S.C. §103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed February 16, 2006. Applicant submits that claims 1-32 are in condition for allowance and respectfully request that claims 1-32 be passed to issuance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Should any fees be due, please debit Deposit Account No. 07-1185 upon which the undersigned attorney is allowed to draw.

Respectfully submitted,

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